DEPARTMENT OF ...LTH & HUMAN SERVICES

Public Health Service

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FOOD & DRUG ADMINISTRATION
466 FERNANDEZ JUNCOS AVENUE
SAN JUAN, P.R. 00901-3223

January 16, 2002

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER
SJN-02-05

Mr. Dennis Alequin Rodríguez
President
Alero Corporation
P.O. Box 602
Bayamón, Puerto Rico 00960

Dear Mr. Alequin Rodríguez:

On November 16, 20 and 26, 2001 the Food and Drug Administration (FDA) conducted an inspection of your human and veterinary drug warehouse, Alero Corporation at 3G5 Lomas Verdes Ave., Bayamón, Puerto Rico. A review was conducted of the inspectional information. The review finds the products are adulterated within the meaning of section 501(a)(2)(B) of the Federal Food Drug and Cosmetic Act (the Act) and Title 21, Code of Federal Regulations (CFR), parts 211, Current Good Manufacturing Practices for finished pharmaceuticals.

1. Prescription drug products stored at your firm, with temperature range controls from 68 degrees F to 77 degrees F, were not held in accordance with the label requirements to ensure the identity, strength, quality and purity of the drug products as set forth in 21 CFR 211.142(b). There were no reading logs or data of temperatures and relative humidity conditions of the warehouse since March 13, 2001 as required. The temperature indicator at your firm during the inspection indicated a storage temperature of 81.7 degrees F. The air conditioning system is not run continuously and is turned off overnight, weekends and holidays.

2. Written procedures describing the warehousing of drug products were not implemented as required by 21 CFR 211.142 and the Standard Operating Procedures manual, dated July 1998, was not officially approved as required by 21 CFR 211.100.

You should take prompt action to correct these deviations and prevent their future recurrence. Failure to make prompt corrections could result in regulatory action without further notice. Possible actions include seizure and/or injunction.

Please notify this office in writing, within 15 working days of receipt of this letter, of specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective actions can not be completed within 15 working days, state the reason for delay and the time within which corrections will be completed.

Your reply should be sent to the Food & Drug Administration, San Juan District Office, 466 Fernandez Juncos Ave., San Juan, PR 00901-3223, Attention: Mary L. Mason.

Sincerely,

Mildred R. Barber
District Director